Proposed Maximum Residue Limit PMRL2016-39

Spiromesifen

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various commodities to the product label of Oberon™ Flowable Insecticide-Miticide, containing technical grade spiromesifen, is acceptable. The specific uses approved in Canada are detailed on the label of Oberon™ Flowable Insecticide-Miticide, *Pest Control Products Act* Registration Number 28905.

The evaluation of this spiromesifen application indicated that the end-use product has merit and value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for spiromesifen is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by Canada's Notification Authority and Enquiry Point .

The proposed MRLs, to replace or be added to the MRLs already established for spiromesifen, are as follows.

Table 1 Proposed Maximum Residue Limits for Spiromesifen

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Spiromesifen	2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4] non-3-en-4-yl 3,3-dimethylbutanoate, including the metabolite 4-hydroxy-3-(2,4,6-trimethyl phenyl)-1-oxaspiro[4.4]non-3-en-2-one	20	Leafy vegetables (Crop Group 4-13)[2], mint tops
		8.0	Leaf petioles vegetables (Crop Subgroup 22B)
		4.0	*Brassica* head and stem vegetable group (Crop Group 5-13)[3]
		2.0	Low growing berries (Crop Subgroup 13-07G)[4]
		0.9	Sorghum
		0.8	Fruiting vegetables (Crop Subgroup 8-09)

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
		0.15	Meat byproducts of cattle, goats, hogs, horses and sheep[5], wheat bran, wheat germ
		0.08	Dried shelled pea and bean, except soybean (Crop Subgroup 6C)[6]
		0.06	Wheat
		0.03	Fat of hogs, meat of cattle, goats, hogs, horses and sheep[7]
		0.02	Milk[8], popcorn grain, sweet corn kernels plus cob with husks removed

[1] ppm = parts per million
[2] This MRL is to replace the current established MRL on CSG 4A. The new proposed MRL is to be extended to all crops within CG 4-13.
[3] This MRL is to replace the current established MRLs on CSG 5A and 5B. The new proposed MRL is to be extended to all crops within CG 5-13.
[4] This MRL was previously established for strawberry alone. The MRL will be extended to the whole CSG 13-07G.
[5] This MRL is to replace the current established MRL of 0.05 ppm on meat byproducts of cattle, goats, horses and sheep.
[6] This MRL is to replace the current established MRL of 0.02 ppm on dry shelled beans. The new proposed MRL is to be extended to all crops within CSG 6C.
[7] This MRL is to replace the current established MRL of 0.01 ppm on meat of cattle, goats, horses and sheep.
[8] This MRL is to replace the current established MRL of 0.01 ppm on milk.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

The MRLs proposed for spiromesifen in Canada are the same as corresponding American tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs[1] listed for spiromesifen in or on any commodity on the Codex Alimentarius Pesticide Residues in Food and Feed webpage.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spiromesifen up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

New residue data from field trials conducted in the United States were submitted to support the domestic use of Oberon™ Flowable Insecticide in/on wheat, sorghum, dry peas, celery, mint, sweet corn, popcorn, tomatoes and bell and nonbell peppers. Previously reviewed residue data from field trials conducted in/on strawberries, dry beans, succulent-shelled beans or edible-podded beans were reassessed in the framework of this petition. Spiromesifen was applied at the proposed and exaggerated rates, and harvested according to label directions. In addition, processing studies in treated wheat and mint were reviewed to determine the potential for concentration of residues of spiromesifen into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for spiromesifen was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs in/on various crops.

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

Commodity	Application Method/ Total Application Rate (g ai/ha)[1]	Preharvest Interval (days)	Minimum Residues (ppm)	Maximum Residues (ppm)	Experimental Processing Factor
Head lettuce	Foliar / 451-465	6-9	0.16	4.65	NA
Leaf lettuce	Foliar / 451-466	7-8	0.51	9.99	NA
Spinach	Foliar / 449-476	6-9	0.24	8.65	NA
Mustard greens	Foliar / 448-453	6-8	0.63	10.03	NA
Mint tops	Foliar / 842-869	6-8	1.72	10.97	1.5 (oil)
Celery	Foliar / 446-461	7	0.02	4.24	NA
Broccoli	Foliar / 445-462	7-10	<0.02	0.71	NA
Cabbage	Foliar / 451-466	6-9	<0.02	1.91	NA
Strawberry	Foliar / 843-863	2-4	0.23	1.64	NA
Sorghum	Foliar / 297-309	28-30	0.02	0.68	NA
Bell Pepper	Foliar / 436-453	1	<0.02	0.17	NA
Nonbell pepper	Foliar / 438-441		0.03	0.34	NA
Tomato	Foliar / 445-459		0.04	0.45	NA
Dry shelled peas	Foliar / 631-676	9-11	<0.02	0.06	NA
Dry shelled beans	Foliar / 634-726	9-10	<0.02	<0.02	NA
Wheat	Foliar / 295-309	28-30	<0.02	0.05	4.9 (bran) 3.8 (germ)
Popcorn grain	Foliar / 303-303	28-29	<0.02	<0.02	NA
Sweet corn (K+CWHR)	Foliar / 291-305	28-30	<0.02	<0.02	NA

[1] g a.i./ha = grams of active ingredient per hectare

Based on the dietary burden and residue data, MRLs of 0.03 ppm in meat of cattle, goats, hogs, horses and sheep, 0.03 ppm in fat of hogs, 0.15 ppm in meat by-products of cattle, goats, hogs, horses and sheep and 0.02 ppm in milk to cover total residues of spiromesifen are also proposed.

Following the review of all available data, the MRLs as proposed in Table 1 are recommended to cover residues of spiromesifen. Residues of spiromesifen in these crop and livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.